



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
FAX: 425-483-4996

July 2, 1999

VIA FEDERAL EXPRESS

In reply, refer to Warning Letter SEA 99-27

Mr. Eric Jensen, Hospital Administrator  
Kittitas Valley Community Hospital  
603 South Chestnut Street  
Ellensburg, Washington 98926

WARNING LETTER

Dear Mr. Jensen:

On June 8 and 9, 1999, an inspection of your medical gas repacking operation at Home Respiratory Resources, 302 East 2<sup>nd</sup> Avenue, Ellensburg, Washington, by FDA Investigator Connie Rezendes revealed serious deviations from the Good Manufacturing Practice Regulation (Code of Federal Regulations, Title 21, Part 211), causing the oxygen repacked by this firm to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). Among the deviations observed, was the following:

Failure to properly calibrate the oxygen analyzer according to the manufacturer's directions using calibrated gases, oxygen and nitrogen, as specified.

The above listed violation is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Federal agencies are advised of the issuance of all Warning Letters concerning drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct this deviation. Failure to do so may result in regulatory action by FDA without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective

action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Richard S. Andros, Compliance Officer, at the address indicated on the letterhead.

Sincerely,

*Celeste M. Corcoran*

*for*

Roger L. Lowell  
District Director

copy: Robin P. Lacey, Supervisor  
Home Respiratory Resources  
302 East 2<sup>nd</sup> Avenue  
Ellensburg, Washington 98926